IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO PLAINTIFFS: **All Wave II TVT Cases** **Pamela Bailey et al v. Ethicon, Inc, Et. Al.**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE** **2:12-CV-01700**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL OPINION TESTIMONY OF JOYE K. LOWMAN, M.D. AS WELL AS HER SPECIFIC OPINIONS IN THE CASE OF PAMELA BAILEY

I. PRELIMINARY STATEMENT

Now come Plaintiffs seeking to exclude, or to limit in the Court's discretion, the expert testimony of Dr. Joye K. Lowman, M.D. ("Dr. Lowman"), pursuant to Federal Rule of Evidence ("Rule") 702 and the standards set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharms. Inc.* 509 U.S. 579 (1993) and as adopted by the Fourth Circuit. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(Federal law governs the admissibility of expert testimony) Dr. Lowman's testimony is in the Expert Report of [Dr. Lowman] ("Lowman Report")[1] and in her deposition testimony of June 24, 2016 regarding TVT.[2]

Dr. Lowman seeks to proffer general opinions regarding the TVT-O manufactured and

[1] The Lowman Report is attached hereto as Exhibit A. Future citations to the Lowman Report are in the form (Ex. A, ___.)
[2] Dr. Lowman's deposition testimony is attached hereto as Exhibit B. Future citations to it will be in the form (Ex. B, ___:___.)

marketed by Ethicon for the treatment of SUI, as well as case specific opinions in the pending case of Pamela Bailey ("Ms. Bailey").[3] Both general and case specific opinions are set forth in the her Case Specific Expert Report of Joye K. Lowman, M.D. MPH, (Lowman Bailey Report") and in her deposition testimony of June 24, 2016. Plaintiffs generally move now to limit some of Dr. Lowman's opinions regarding Ethicon's SUI devices as more fully set forth herein. In addition, Ms. Bailey likewise moves to exclude some of Dr. Lowman's case specific opinions in her case. Dr. Lowman's opinions are subject to exclusion under applicable law as set forth herein.

II. LEGAL STANDARD

Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702.

The Supreme Court in *Daubert* assigned to district courts a "gatekeeping function" in determining whether expert testimony is both reliable and relevant and, thus admissible, under Rule 702. 509 U.S. 579. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)("Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable,") (internal citations and quotations omitted.). Under both *Daubert*, 509 U.S. 579, and Rule 104(a) -

[3] Dr. Lowman's opinions in Ms. Bailey's case are proffered in the Lowman Bailey Report attached hereto as Exhibit C. Future citations to it will be in the form (Ex. C, ___.), and in her case specific deposition testimony from June 16, 2016 proffered in Ms. Bailey's case. That deposition testimony is attached hereto as Exhibit D. Future citations to it will be in the form (Ex. D, ___:___.)

- the statute imposing a duty on courts to decide preliminary questions regarding the qualifications of witnesses and/or the admissibility of evidence--this Court must determine whether the requirements of Rule 702 are met before any expert testimony can be presented to the jury. *See, Cooper*, 259 F.3d at 199; (the district court determines whether the methodology employed by the expert is "scientifically valid" and whether that methodology is applicable to the facts in issue). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and "the proponent of the testimony must establish its admissibility by a preponderance of proof." *See Cooper*, 259 F.3d at 199 (citing to *Daubert*, 509 U.S. at 592 n. 10; *see also Hines v. Wyeth*, C. A. No. 2:04-0690, 2011 WL 2792436 at *2 (S.D.W.Va. July 14, 2011).).

Additionally, when considering medical expert opinion, the applicable legal standard requires a court to determine whether the expert made an appropriate differential diagnosis, that is, whether she ruled in (or out) the potential causes of a plaintiff's injury in determining what caused it in order for the opinion to be found reliable. *See Westberry v. Gislaved Gummi AB,* 178 F.3d 257, 262 (4th Cir. 1999) ("Differential diagnosis, or differential etiology is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated."). In short, reliable differential diagnoses pass scrutiny under *Daubert* but unreliable ones do not. *See Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 702 (S.D.W. Va. 2014). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and "the proponent of the testimony must establish its admissibility by a preponderance of proof." *See Cooper*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592, n.10); *see also Hines v. Wyeth*, C. A. No. 2:04-0690, 2011 WL 2792436 at *2 (S.D.W. Va. July 14, 2011).

III. LEGAL ARGUMENT

A. DR. LOWMAN'S GENERAL OPINIONS SHOULD BE EXCLUDED OR LIMITED

1. Dr. Lowman's Opinions Insofar As They Exceed The Scope Of Her General Report Must Be Excluded.

As this Court has previously held, an expert should not be allowed to testify "outside the scope of [his] expert opinion." *See Huskey v. Ethicon*, C. A. No. 2:12-cv-05201, 2014 WL 3861778 at *5 (S.D.W. Va. August 6, 2014). Each of Dr. Lowman's reports are limited to one Ethicon SUI device, the TVT, and since Ms. Bailey was implanted with a TVT-O, they are further limited to that specific device. (See Ex. A.) (See also Ex. C.) Any opinions she purports to give outside that scope should be excluded. Likewise to be excluded are any opinions on the TVT-O that are not based on Dr. Lowman's experience.[4]

Crucial to understanding Dr. Lowman's testimony is that her background and experience is exclusively as a clinician. From the day she left her post-doctoral fellowship until the present she has been employed by Kaiser Permanente as a clinical physician, and as she has risen through the ranks, she has been promoted to various administrative positions. Notably, none of these positions have included her supervision of other physicians or entailed responsibilities for fashioning warnings, conducting research, or fashioning protocols. Instead, what is presented by Dr. Lowman is a physician who has installed 800 plus TVT retropublic devices over her tenure, with NO (zero) complications. (Ex. A, 1-3, 10.) (Ex. B, 26:22-27:7.) She is a physician who prior to leaving her fellowship made the decision not to utilize TVT-O:

> Q: Doctor, in your report you indicated that you have placed approximately 800 TVT and TVT-O devices. Is that correct? I'm at page 2.
> A: Yes.
> Q: And do you use both TVT and TVT-O?
> A: No.
> Q: What do you use --
> A: The TVT.
> Q: -- currently? Did you ever use TVT-O?
> A: I have used it before, yes.

[4] Dr. Lowman previously rendered an expert report dated August, 2015 relating to the Prolift which was the subject of an earlier motion to limit her opinion previously filed with the Court.

> Q: And is there a reason why you exclusively use TVT today?
> A: Yes. The retropubic route has a lower risk of pelvic pain and groin pain and has a higher success rate --
> Q: I see.
> A: than obturator slings.
> Q: And was there a date that you can point to that that was the date that you felt that the evidence that you have just recited was sufficient for you to not use TVT-O: anymore?
> A: No.
> …
> Q: I see. So while you were either in residency or fellowship, you made that determination?
> A: That's correct .

(Ex. B, 23:9-24:18.)(objections excluded for readability).

All of Dr. Lowman's knowledge as to complications have come from literature review, and reading pronouncements from several associations of specialists, and by participating in six revision surgeries on referred cases from other physicians. She has never had a complication in her 800 plus TVT insertions.[5] She has no direct experience with TVT-O beyond her residency and fellowship and, in fact, most critically declined to use it because of her judgment as to patient safety and outcomes. (Ex. B, 23:19-24:18.) Therefore, since her clinical experience does not include the TVT-O she fails by lack of knowledge and experience to be able to offer reliable opinions on the device at the first step. Her opinions must be excluded. *See* Rule 702.

2. Dr. Lowman's Opinions On Material Science Or Defective Design Must Be Excluded.

Second, since her opinion is based completely on her clinical experience and literature review, she must not be allowed to opine on various material qualities of the TVT-O including pore size, degradation; shrinkage or contracture; stiffness; and other design features. All are areas in which Dr. Lowman's general opinion report makes conclusions and opinions that are not based

[5] (Ex. A, 10)(Ex. B, 26:7-27:13.)

upon personal experience or knowledge, but are nothing more than *ipse dixit* assertions that fail to satisfy Rule 702: *See Huskey*, 29 F.Supp.3d at 725.

> Q: Do you intend at trial to give an opinion on the characteristics of polypropylene in the body?
> A: If I'm asked.
> Q: And here I guess these are going to be my questions, then. Are you a materials scientist?
> A: I'm a scientist, and so I'm able to evaluate published literature, whether it's about materials or whether it's about clinical outcomes or something else.
> Q: And have you worked with polymer chemicals in your career in terms of analyzing them, analyzing their characteristics, their strengths, their weaknesses?
> A: No.
> Q: Have you conducted any tests on the polypropylene materials that constitute or that makeup a TVT device?
> A: No

(Ex. B, 42:11-43:3.)

> …
> And when you take the part, the section out, do you participate in the pathology analysis of the removed section?
> A: I don't.
> Q: You don't participate either in the gross or the microscopic inspection of the removed section; is that right?
> A: That's correct.
> Q: Now, have you done any work on the properties of the polypropylene itself? For example, rates of oxidation or degradation?
> A: When you say work, what do you mean?
> Q: I mean have you performed any testing?
> A: No.
> Q: Have you participated in any kind of trials in which you would implant polypropylene material and then excise it and look and see what had happened …while it was implanted?
> A: No. But I don't need to, to be able to read the results of the people that have --
> Q Right.
> A: -- and those results have been published –

(Ex. B, 48:6-49:20.)(objections excluded for readability)(more complete transcripts are provided in Exhibit B to allow for context and continuity beyond the highlighted sections).

Being no materials expert, never having designed an implantable medical product; having conducted no gross or microscopic pathology; conducted no studies, collected no data, Dr.

Lowman cannot be allowed to recite items she has read and embraced as competent expert testimony. It is simply beyond the scope of her experience and such opinions must be excluded. *See* Rule 702.

3. Dr. Lowman's Opinions On The Adequacy Of The IFU Accompanying the TVT-O Must Be Excluded.

Likewise, Dr. Lowman's general opinion about the adequacy of the IFU language is also unreliable. She has never written an IFU; and did not consult with texts that would have been important to evaluate or to understand whether the complications placed on the original IFU were immediate risks of surgery, or were permanent chronic risks of the mesh itself; to understand the severity of complications; to understand the rate of complication. Without such experience, knowledge, or expertise in drafting, all she could do was to read other peoples' work, and here, it is even clear that she did not apprise herself of the full pros and cons of the literature. Her opinions on the adequacy of the IFU should be excluded as unreliable. *See Daubert*, 509 U.S. 579.

> Q: I mean, the purpose of the IFU is to apprise learned intermediaries of the adverse reactions that they may encounter? … Correct?
> A: I would say not necessarily. In a perfect world in my opinion what you are stating should be true.
> Q: Yes.
> A: But I think many times, in the same way that hospitals put things on their consent forms that in all likelihood would -- have never happened – much of what goes on a consent form or an IFU is to protect oneself from the litigation, to make sure that they've sort of warned about everything that they've been told they should warn about.
> Q: And if that's the purpose, then the --
> A: I'm not saying that's the purpose.
> Q Well, if you're --
> A: I'm just saying it's not necessarily true that everything that they put in the IFU has been experienced by someone. That's what I am saying.
> Q: Well, would you think that a physician who receives the IFU could rely that all of the adverse reactions that he or she may encounter are going to be included?
> A: No.

(Ex. B, 82:6-83:14.)(objections excluded for readability).

In addition, this Court has also previously held that medical experts are not qualified to offer opinion regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed. *See Sederholm v. Boston Scientific Corp.*, C. A. No. 2:13-cv-12510, 2016 WL 3282587 at *13 (S.D.W. Va. June 14, 2016)(excluding urologists' expert opinions on the adequacy of defendant's IFU that he based only on the risks he observed in his practice). Dr. Lowman now seeks to offer opinions regarding the adequacy of the IFU accompanying the TVT-O based on the same type of experience that this Court has previously found insufficient and her opinions must be excluded.

B. DR. LOWMAN'S CASE SPECIFIC OPINIONS AS TO THE TVT-O IMPLANTED AND EXCISED IN MS. BAILEY SHOULD BE EXCLUDED

Dr. Lowman conceded in her testimony that the exposure observed by Ms. Bailey's physician, Dr. Adam, in 2005 was caused by the TVT-O mesh:

> Q:.Now, there is no doubt that the – not erosion but exposure that Miss Bailey suffered, was caused physically by the mesh; isn't that right?
> MR. RUMANEK: Objection to form.
> A: It was associated with the mesh, yes.

(Ex. D, 49:6-11.)

Several other of Dr. Lowman's case specific opinions must be excluded because she failed to follow and to apply a scientific methodology. *See Daubert*, 509 U.S. 579 (expert opinion not grounded in reliable methodology must be excluded.). First, Dr. Lowman seizes upon a single word, "taut," in a medical record to opine that the installing physician placed the TVT-O too tightly. She comes to this conclusion in the face of, and only after discounting and disregarding very strong evidence contrary to hers. She claims that the tightness caused retention when in fact the medical record is completely silent about retention for over four years:

> Q: But what I am asking very specifically is, is there any notation in a medical record that you have reviewed that shows a complaint of voiding dysfunction between 4/20/01 and 5/28 of '02?
> A: I don't believe so. I think if I'd seen that, I would have noted it.[6]

(Ex. D, 30:22-31:3.)(objections excluded for readability).

Dr. Lowman points to her own practice of detensioning after twelve weeks instead of the IFU and Ethicon practice manual's instruction calling for detensioning immediately:

> Q: And on those occasions you've waited 12 weeks because that is the optimum time to effect a proper adjustment…is that right?
> A: Yes. But let me qualify that by, I don't see patients in complete retention, so -- complete retention is where they're not voiding at all or maybe voiding 20 or 30 CCs with residuals of 300, 400, et cetera. It may behoove you to adjust that sling sooner and possibly to consider repeating the sling if there is -- voiding dysfunction is that severe. So I usually see mild voiding dysfunction -- the patient is not, you know, suffering with a catheter and that kind of thing for three months -- and so it's more reasonable to wait three months in that situation, and that's what I customarily do.
> Q: I see. Your procedure, based on your experience and expertise and based on the evidence, differs from the advice that Gynemesh was giving to surgeons in 2000; is that right?
> A: What I currently do is different than what is listed here, yes.

(Ex. D, 25:15-26:20.)(objections excluded for readability).

But in either case, **there is no support in the medical record** that Ms. Bailey had any complaint until fall, 2004 at the earliest. Despite this being a dispositive null finding, Dr. Lowman, nevertheless, offers the opinion that the root cause is overtensioning. There is no showing that she utilized a differential diagnosis to rule out other plausible causes and significant showing that she overlooked information that did not support her diagnosis. Certainly, there is no evidence in the medical record of an exposure until the fall of 2004. These opinions must be excluded. *See*

[6] A lengthy discussion extending between pages 30-34 of the case specific deposition (See Ex. D, 30-34) traces the assertion that Ms. Bailey's medical record showed no voiding dysfunction attributable to the SUI device from the date of implant through four years afterward.

Huskey, 29 F.Supp.3d at 702 (reliable differential diagnoses pass scrutiny under *Daubert* but unreliable ones do not.).

Finally, Dr. Lowman reduces Ms. Bailey's complaints of painful sex by the facile opinion that because Ms. Bailey's TVT-O device was explanted, there was no way for the device to be continuing her pain:

> A: Certainly she could have, you know, vaginal atrophy. She had collagen injections that can sometimes cause pelvic pain as well, so there are other potential risks that could be contributing to dyspareunia if it is present currently, but it would be unlikely that if her dyspareunia was due to the mesh erosion or due to the sling, that after excising the vaginal portion of the sling, that she would still have dyspareunia due to the sling.
> Q: I guess I'm at a little bit of a disconnect here. What I am hearing is that you go in and you excise the portion and then it's gone, and so what is -- there is nothing there to hurt. Is that what I am hearing?
> A: Yes. In the vaginal compartment, yes.
> Q: But here is my question. I mean, the TVT was implanted for four years. The whole theory of a TVT device is that there will be ingrowth of some form of fibrous material, some scar or, you know, vascularity in her nerves; giant cells. All of those things, the whole design of this product, is to allow ingrowth; isn't that right?
> A: Tissue ingrowth in terms of fibroblast and collagen, yes.
> Q: So when you excise the mesh, it's not like you're slipping a little card out of your camera? You actually are cutting away material, which includes living material; isn't that right?
> A: I'm not sure what you mean by living material.
> Q: I mean, the stuff that grows in through the inflammatory process is alive, isn't it?
> A: I'm not sure what you mean by that.
> Q: I mean, these are living cells that grow into the mesh material?
> A: There is tissue ingrowth, yes.
> Q: So when you cut out the mesh, you're cutting out that tissue with it? I mean, that's just how you resect it; isn't that right?
> A: Not exactly. I mean, you dissect the sling out, so you do some separation of the sling from the surrounding tissue and then remove the sling. There should -- there probably is some tissue that gets removed with the sling.
> Q: I guess my question is, why would it be not just as likely that the removal of the sling would result in some inflammatory response that could cause either a continuing pain or even enhanced pain as a result of that removal operation? Wouldn't that have to be on your differential?
> A: That's a possibility. It's just unlikely.[7]

[7] Discussion of dyspareunia and Dr. Lowman's methodology runs from pp. 49-63 (Ex. D, 49:13-63:5.).

(Ex. D, 52:1-54:13.)(objections excluded for readability).

This glib syllogism is not a scientific opinion at all, but merely a debater's point, and it should be excluded as speculation, particularly because there is ample evidence to support that it is nearly impossible to remove TVT-O devices entirely. *See Huskey*, 29 F.Supp.3d at 727-29. Her opinion is also particularly suspect because Dr. Lowman had access to an IME by Dr. Walmsley with specific findings as to Ms. Bailey's vaginal pain and dyspareunia.[8] Dr. Lowman must discount and ignore Dr. Walmsley's finding in making her opinion, and by so doing exposes a biased differential diagnosis. Her opinion must be struck.

While a physician need not perform every diagnostic test and/or rule in or out every possible diagnosis for his differential diagnosis to pass legal muster, she must show that she "employed sufficient diagnostic techniques to have good grounds for his or her conclusion." *See Huskey*, 29 F.Supp.3d at 717. And, as said, she must show the same level of "intellectual rigor" in rendering her expert opinions that she brings to her practice. *See Trevino*, 2016 WL 2939521 at *12. (This Court excluding medical expert opinion about product design where the doctor did not review the defendant's operating materials, thereby not showing the level of intellectual rigor he would bring to his clinical practice.).

Finally, Dr. Lowman dismisses as "speculation" future problems Ms. Bailey will suffer because of her TVT-O implant but refuses to countenance that it is also mere speculation to say that Ms. Bailey will not experience such problems. This clearly exposes a logical disconnect. Dr. Lowman should not be permitted to opine that Ms. Bailey will not experience future difficulties from mesh:

[8] See excerpts of Dr. Walmsley deposition setting out his physical IME findings from an examination that took place only weeks ago. This is Exhibit E attached hereto at 6:19-20; 27:3-28:16.

> Q: "It is unlikely Miss Bailey will suffer any further complications from her TVT." Your first sentence is, "It would be speculative to suggest that Miss Bailey will suffer any further complications"; is that correct?
> A: That's correct.
> Q: And it's also speculative to suggest that she will not suffer further complications; isn't that right?
> A: No. We have a significant amount of evidence and data that supports the fact that the incidence of complications with mid-urethral slings, including the TVT, is very low, and that certainly includes TVTs that have been revised or excised as well, partially excised.
> Q: I guess my point would be that you really have no idea about Mrs. Bailey's prognosis as we sit here today, do you?
> A: No. Actually, I do. We have -- you know, 3 million women have been implanted with mid-urethral slings, and we have great -- large randomized control trials, the Cochrane Review that includes 12,000 women that gives us an indication and actual incidence rates of complications with mid-urethral slings.
> Q: Well, you know, this message from the [AUGS] president that I was handed this morning, it has an interesting line in it, and I'm going to read it to you. It says, "The mid-urethral sling is the most studied procedure for SUI medical literature. However, the majority of that data is from outside the United States, and there remains gaps in the literature around longer-term outcomes. The board has approved the development of an SUI surgery registry to track physician-reported process ….

(Ex. D, 64:5-65:24.)(objections excluded for readability).[9]

Dr. Lowman reached her opinions on the basis of the materials provided to her and she indicated that the materials were sufficient to allow her to reach her conclusions. But she did not perform an IME examination. She had access to Dr. Walmsley's IME results but chose to discount or to ignore those "real time" findings. If there were a true differential diagnosis at work, Dr. Lowman would be bound to incorporate and to utilize all information available, not just to take those few words that support a conclusory outcome reached only by ignoring the best evidence available. Such ex post facto reverse engineering renders her opinions suspect and they should be excluded. In short, in failing to conduct an IME, Dr. Lowman proffered opinions that deviate from the usual clinical practice of a physician and are unreliable. *See Trevino v. Boston Scientific Corp.*,

[9] (Ex. D, 61:5-70:13)(explores the anecdotal basis for her conclusions.).

C. A. No. 2:13-cv-01617, 2016 SL 2939521 at *12 (S.D.W. Va. May 19, 2016)(holding that an expert must "reliably appl[y] his methodology to the facts of the case with the same level of intellectual rigor that characterizes the practice of an expert in that field.")(internal quotations and citations omitted.).

IV. CONCLUSION

For reasons of the forgoing, the general opinion of Dr. Lowman as set forth herein, must be excluded or limited to the scope of her expert report and her deposition testimony as required by federal law. Additionally, Plaintiff Ms. Bailey, likewise moves to limit or exclude the case specific opinions proffered by Dr. Lowman for all of the reasons set forth herein.

Date: July 21, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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